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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,918	08/22/2005	Werner Bieberschulte	4358-16	4213
23117 7590 03/01/2010 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
BASQUILL, SEAN M				
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1612				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/522,918

**Applicant(s)**

BIEBERSCHULTE ET AL.

**Examiner**

Sean Basquill

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 15-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants are advised, in future correspondence with the office, to reflect the change of examiners from SARA CLARK to SEAN BASQUILL.

#### ***Status of the Claims***

1. Claims 1 and 10-12 have been amended, and new claim 39 entered. Claims 15-38 remain withdrawn as directed to a nonelected invention. Claims 1-14 and 39 are presented for examination.

#### ***Previous Rejections***

2. Applicants' arguments, filed 11 September 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Terminal Disclaimer***

3. The terminal disclaimer filed on 30 November 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patents 5,563,140 and 6,573,265 has been reviewed and is NOT accepted.

It does not include a recitation that any patent granted shall be enforceable only for and during such period that said patent is commonly owned with the application(s) or patent(s) which formed the basis for the double patenting rejection. See 37 CFR 1.321(c)(3).

***Claim Rejections - 35 USC § 112 Second Paragraph***

4. While the examiner has withdrawn the previous rejections applied under 35 U.S.C. 112, second paragraph, addressing a matter of claim interpretation is appropriate at this time. Applicants claims are directed to a “pharmaceutical formulation,” and while particular uses to which the formulation may subsequently be put follow such descriptive language (such as “for trans-tympanic or intra-transtypmanic administration,” which the examiner incidentally would consider language reciting largely equivalent actions, as both trans-tympanic and intratranstympanic administration of a composition is designed to permit the composition, and more pointedly the active agents contained therein, to cross the tympanic membrane; one method simply takes advantage of the presence of a tympanostomy tube), such language merely recites an intended use of the composition as claimed. *See* MPEP 2111.02(II) (indicating claim preambles which state the intended use of a claimed invention, rather than setting forth any distinct definition or limitation of the invention claimed, are not considered a limitation of the claim and are of no significance to the claims’ construction). As such, the phrases “for trans-tympanic or intra-transtypmanic administration” are immaterial to the examiner’s construction of the claim and search for art relevant thereto.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-10 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,563,140 ("Ehrenberger"), in view of U.S. Patent 6,093,417 ("Petrus"), as put forth in paragraph 8 of the office action mailed 11 May 2009.

Applicants' arguments have been fully considered and are deemed unpersuasive. While Ehrenberger may direct particular embodiments of the invention described therein to the intravenous administration of quinoxaline-2-one compounds, the totality of the disclosure is not so limited when considered by one possessing ordinary skill in the art. Indeed, the disclosure of Ehrenberger particularly indicates only that "applications of these pharmaceuticals could be the treatment of glutamate-induced and glutamate-receptor-mediated neurotoxic dysfunctions such as functional disturbances of the inner ear, like tinnitus and impaired hearing." (C.2, L.57-60). This disclosure provides sufficient teaching to suggest to the skilled artisan that local administration of quinoxaline-2-one compounds may be advantageously used to treat functional disturbances of the inner ear, as *inter alia* Petrus clearly indicates that the local otic application of therapeutic drugs advantageously delivers active agents in close proximity to the target tissues. (C.3, L.41-52).

Applicants have, in essence, attempted to impose on the examiner a requirement that legally does not exist; namely that the prior art relied upon by the examiner specifically disclose teachings relevant to addressing the problems that the applicants' invention is directed to addressing. Such a rigid requirement is incompatible with the legal analysis of obviousness binding on the examiner. See *KSR International Co. v. Teleflex, Inc.*, 82 USPQ2d 1385, 1397 (U.S. 2007) (indicating that it is error to assume that a person of ordinary skill would be led only to those elements of prior art designed to solve the same problem). Stated properly, the examiner

bears the burden simply to articulate reasoning with some rational underpinning to support their legal conclusion of obviousness. (*Id. at* 1396). Neither is the examiner bound to the express language nor precise teachings of the prior art, as they are entitled to take account of the inferences and creative steps that a person of ordinary skill in the art would employ. (*Id.*) Within such a framework, it must be remembered that patents and prior art are relevant for all that they expressly contain and reasonably suggest to the skilled artisan. *See* MPEP 2123 (indicating art is relevant for all that it contains, not simply the particular problems with which they may be concerned). Given this understanding, the skilled artisan would clearly have reason to extend the utility of the permeation-enhanced otic compositions of Petrus beyond the narrow antiinflammatory and antiinfective uses particularly described; the disclosure repeatedly addresses the improved delivery to the cochlea of "active agents," not simply "antiinflammatory agents," or "antibiotic agents" which constitute the preferred embodiments of the Petrus invention.

In addition, the examiner considers the purported "surprising and advantageous" properties of the composition claimed to be neither surprising nor unexpected, as the advantages disclosed therein can be found throughout the disclosure of Petrus. Applicants have, in essence, dubbed surprising that which is well-known within the otic arts.

6. Claims 1-14 stand and Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrenberger as modified by Petrus as applied to claims 1-10 and 12 above, and further in view of U.S. Patent 5,446,070 ("Mantelle") as put forth in paragraph 8 of the office action mailed 11 May 2009.

Applicants' arguments have been fully considered and are deemed unpersuasive for the reasons put forth above.

### ***Double Patenting***

7. Claims 1-14 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 7, and 9 of U.S. Patent No. 5,563,140 in view of Mantelle and Petrus as put forth in the previous action.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

8. Claims 1-14 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 7, and 10 of U.S. Patent No. 6,573,265 in view of Mantelle and Petrus as put forth in the previous action.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

### ***Conclusion***

No Claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill



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/JEFFREY S. LUNDGREN/

Primary Examiner, Art Unit 1639